FDA 510(k) Premarket Notification

K820787 HELENA ABNORMAL HBA2 QUIK COLUMN CONTROL

CLEARED

Apr 8, 1982
16 days to decision

K820787 · Product code: **JCM** · Hematology
Source: https://www.510kdatabase.net/k820787/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hemoglobin, Abnormal (JCM)
Date received	Mar 23, 1982
Decision date	Apr 8, 1982
Days to decision	16 days
Third-party review	No

APPLICANT

Company	**Helena Laboratories**
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k820787/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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